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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,671

Applicant(s)

TJELLSTROM ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13 and 15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Art Unit: 1644

1. In view of the Brief filed on 7/16/2004, PROSECUTION IS HEREBY REOPENED as set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-10,13,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassig (U.S. Pat. No. 4,676,982) in view of Hardie (U.S. Pat. No. 4,477,432), Park et al. and Ibbotson et al.

Hassig teaches and claims a method of treating chronic inflammatory diseases of the bowel, including ulcerative colitis and Crohn's disease, by intravenously administering an effective dose of polyvalent immunoglobulin (see entire document,

Art Unit: 1644

e.g., Abstract and claims). Inflammatory bowel disease is a form of mucosal inflammation. Hassig teaches that the immunoglobulin preparation is intact IgG obtained from blood serum fractions (i.e., is a pooled human polyclonal immunoglobulin preparation, see column 1, especially lines 32-48). SANDOGLOBULIN (the IgG preparation referred to in the Examples section) is a preparation containing at least about 25% IgG polyclonal antibodies. Hassig also discloses use of a preparation containing at least 70% IgG which is not antigen specific (see claim 1 and column 5, first incomplete paragraph wherein the IgG is prepared from human serum that would contain antibodies of all specificities to which the human had been exposed, and therefore the preparation is not antigen specific). Hassig differs from the instant method by not teaching oral administration and the doses and formulations for oral administration. Hardie teaches that immunoglobulin preparations prepared for intravenous administration could also be administered orally without a loss of therapeutic efficacy (see entire document). Hardie teaches that oral administration of Ig, including IgG, has advantages over parenteral (including intravenous) administration because oral administration avoided the pain of an injection, by provided an easy means of administering the composition, and provided an administration route by which larger doses could be administered if needed (see column 2, especially "Summary of the invention"). Hardie teaches formulating the oral immunoglobulin preparation as part of a pharmaceutically acceptable carrier, and teaches encapsulation of the composition, which would provide an enteric coating (see columns 3-4). Hardie teaches that the formulation administered in the examples of the invention for treatment of enteric infection contained 14 mg/dl (1.4 mg/ml-) of IgG and that 1-8 ml/kg/day was administered (1.4- 112 mg/kg). Thus for an adult of 70 kg, the corresponding dose would be 98-784 mg, which falls within dosage recited in instant claim 7. Park et al. teach the treatment of rheumatoid arthritis using orally administered pooled human IgG at a dosage encompassed by that recited in the claims (see abstract). Thus, the art recognized that orally administered pooled human polyclonal IgG (SANDOGLOBULIN) had been used successfully to treat an autoimmune disease. In addition, Park et al. suggest that the pooled human IgG may neutralize superantigens related to the pathogenic mechanism of rheumatoid arthritis and Ibbotson et al. suggest that superantigens are involved in the pathogenic mechanism in IBD (see page 4, last two paragraphs).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Hassig teaches a method of treating chronic inflammatory diseases of the bowel, including ulcerative colitis and Crohn's disease, by intravenously administering an effective dose of polyvalent immunoglobulin pooled human polyclonal whilst Hardie teaches that immunoglobulin preparations prepared for intravenous administration could also be administered orally without a loss of therapeutic efficacy and Park et al. teach the treatment of autoimmune disease with pooled human IgG. The ordinary artisan would have been motivated to substitute oral administration for intravenous administration because Hardie teaches that oral administration is advantageous compared to parenteral, including intravenous, administration and Park et al. disclose successful treatment of autoimmune disease with orally administered polyclonal pooled human IgG. In addition, Park et al. suggest that the pooled human IgG may neutralize superantigens related to the pathogenic mechanism of rheumatoid arthritis and Ibbotson et al. suggest that superantigens are involved in the pathogenic mechanism in IBD (see page 4, last two paragraphs). Thus one have been motivated to treat IBD with orally administered polyclonal pooled human IgG because of the potential role of superantigens in both IBD and rheumatoid arthritis.

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1644

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Art Unit 1644